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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/513,961	12/20/2004	Michael R Boyd	231119	4710

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/513,961	BOYD ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55 and 57-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-16,18-52,55 and 57-77* is/are rejected.

7)☒ Claim(s) *2,17,53 and 54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-24-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-55 and 57-77 are pending and under consideration in the application. These claims were rejected in the action mailed on February 1, 2007.

2. In the Response of July 24, 2007, the Applicant amended claims 17, 57, 64, and 65.

3. Because this action raises new grounds of rejection, it is made Non-Final.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on July 24, 2007 in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Objections

5. **(Prior Rejection- Withdrawn)** Claims 64 and 65 objected to because of the following informalities: these claims include the phrase "The method of any of claim 39." In view of the amendments to the claim, the objection is withdrawn.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **(Prior Rejection- Maintained in part)** Claims 1, 3-52, 55, and 57-77 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims were rejected on three basis. For the reasons indicated below, the rejection is withdrawn from claim 17, but is maintained against claims 1, 3-16, 18-46, 47-52, 55, and 57-77.

As indicated above, the claims 1, 3-16, 18-46, 47-52, 55, and 57-77 are drawn to the antiviral protein of SEQ ID NO: 1, and antiviral variants and fragments thereof (or methods of use of related compositions thereto). These claims were rejected on the basis that there is inadequate written descriptive support for the claimed inventions to the extent that the claims read on antiviral variants and fragments of SEQ ID NO: 1, or the use thereof. The Applicant traverses this rejection on the basis that it would have been within the skill of those in the art to have made and identified such variants and fragments, and supports the assertion by reliance on the O'Keefe Declaration. In particular, the Applicant asserts that there would have been no undue experimentation in the identification of such variants and fragments. These arguments are not found persuasive.

It is first noted that this rejection is a rejection based on a lack of adequate written description support, not an enablement rejection. As such, the determination as to whether those in the art would have been able to identify mutants and fragments of SEQ ID NO: 1 that retain antiviral activity is not the issue. Rather, the issue is whether the Applicant has provided adequate information to demonstrate that they are in possession of the claimed invention.

With respect to the assertion that the Applicant has described the claimed invention based on the knowledge in the art, and the teachings in the application of methods for the production and identification of mutants and fragments, it is noted that the provision of such methods fails to provide descriptive support for the mutants and fragments that may be so identified. See e.g., *University of Rochester v. G.D. Searle & Co.*, 69 U.S.P.Q.2d 1886, at 1895 (CAFC 2004). Thus, while it would have been within the skill of those in the art to perform the methods to identify variants and fragments, this does not demonstrate possession of such fragments and variants by the Applicant.

The O'Keefe Declaration under 37 CFR 1.132 filed July 24, 2007 is insufficient to overcome this rejection because the fact that the Applicant was able to produce variants and fragments using the methods disclosed in the application does not demonstrate that they were in possession of such at the time of filing, or change the fact that the teachings of the application, which do not disclose the variants and fragments identified in the declaration, fail to provide descriptive support for these fragments or variants.

Because neither the provision of methods for the identification of such variants or fragments is inadequate to provide support for the compounds that may be identified therewith, and as the teachings of the Declaration neither provides evidence that such variants and fragments were in Applicant's possession at the time of filing nor demonstrates that support for such may be found in the application as filed, the Applicant's arguments are not found persuasive. This portion of the rejection is therefore maintained for the reasons above and the reasons of record.

The second basis of the rejection is on the grounds that there is insufficient descriptive support for the genus of nucleic acids described in claim 17. In view of the amendment of this claim to read on any nucleic acid that encodes SEQ ID NO: 1, the rejection is withdrawn from this claim.

Finally, claim 57, drawn to an antibody that binds to scytovirin wherein the antibody comprises an internal image of a gp120 protein of an immunodeficiency virus, was rejected because, while the application indicates that the scytovirin protein is capable of binding to the HIV envelope proteins, the Applicant has not identified what regions of these proteins the proteins react with; and because of this, the application does not teach what regions of these proteins should be included in the internal images of the proteins of the antibodies described by this claim. The Applicant traverses the rejection on the basis that those in the art would have been able to produce and screen for such antibodies with routine experimentation. As was indicated above, this rejection is a written description rejection, and not an enablement rejection. As such, and as described above, whether the invention may be practiced without undue experimentation is not the standard by which the rejection is made.

The Applicant asserts that those of ordinary skill in the art would have been able to select anti-scytoviral antibodies according to the methods described therein. As was described above, the CAFC decision of *Rochester v. Searle* indicates that the provision of a method for the identification of a compound does not provide descriptive support for the compounds that may be so identified. As such, Applicant's argument in traversal is not found persuasive. It is noted

that this portion of the rejection also applies to claim 61. This portion of the rejection is therefore also maintained for the reasons above, and the reasons of record.

8. **(Prior Rejection- Maintained in part)** Claims 37-51, 64-77 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of inhibiting HIV infection of a biological sample, does not reasonably provide enablement for methods of inhibiting HIV virus infection of a host or of inhibiting infection by other viruses than HIV.

The claims were rejected on two grounds.

Claims 37-46 and 64-77 were rejected on the basis that there are insufficient teachings to enable the inhibition of viral infection of a host organism. In view of the Applicant's arguments, the information contained in the O'Keefe Declaration, the articles cited in support thereof, and because the claims are drawn to methods of inhibiting viral infection, but do not require therapeutic benefit, this portion of the rejection is withdrawn.

In addition, claims 37-51 and 64-77 were also rejected on the basis that the application is not enabling for the use of the claimed compositions to inhibit infection by any virus. The rejection is withdrawn from claims 38-40, 74, and 75. The Applicant presented data (in the O'Keefe declaration) that the claimed scytovirins were effective against each of the Ebola, Influenza, and HIV viruses. However, it is noted that the teachings of McFeeters et al., JMB 369:451-61 (cited by the Applicant on page 2 of the O'Keefe Declaration, and provided as an attachment thereto) indicate that scytovirins act as entry inhibitors to HIV. The art also indicates that such compounds would be effective generally against enveloped viruses (see e.g.,

Ziolkowska et al., Acta Biochim Pol 53: 617-26, at 617-18), but does not indicate that they would be effective against non-enveloped viruses, which do not generally rely on surface glycoproteins for cell entry. Thus, the rejection is maintained to the extent that the claims read on the use of the claimed compositions to inhibit infection by non-enveloped viruses. Thus, this portion of the rejection is maintained against claims 37, 41-51, 64-73, 76, and 77 for the reasons above, and the reasons of record.

9. **(Prior Rejection- Maintained)** Claims 60-63 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. In traversal of this rejection, the Applicant asserts that the application is enabling for the use of antibodies that bind to scytovirin as a vaccine. This argument is not found persuasive for two reasons.

First, the present claims 60, 62, and 63 are not limited to the use of the anti-scytovirin antibodies that have an internal image of HIV gp120. Moreover, there is no demonstration or assertion that any antibody that binds to scytovirin would be capable of use in inhibiting viral infection. Moreover, there is also not indication in the present application or in the art that anti-scytovirin antibodies having an internal image of an immunodeficiency virus gp120 would be capable of inducing an immune response, much less a protective immune response, against any virus other than an immunodeficiency virus.

Second, the Examiner does not agree that the application is enabling for the use of antibodies having an internal image of gp120 if an immunodeficiency virus as a vaccine. The portions of the specification referred to by the Applicant discuss only generally the use of anti-scytovirin antibodies for use as vaccines. There is no specific demonstration of such a use.

Moreover, the teachings in the art indicate that the development of an HIV vaccine is a complex issue, wrought with unpredictability; and indicates that to date there has been no successful and protective vaccine developed despite numerous attempts. See e.g., Berkley et al., Lancet, 370: 94-101. Thus, in view of these teachings, especially those on page 95 (indicating that gp120 based vaccines have not been effective), the Applicant's second argument in traversal of this rejection is not found persuasive. The fact that the Applicant suggests the antibodies with internal images of gp120 may be used as vaccines fails to provide enabling support for such a use.

For the reasons above, and the reasons of record, this rejection is maintained.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. **(New Rejection)** Claims 52 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 6,183,961. These claims are drawn to antibodies that bind to the polypeptide of claim 1. Claim 1 reads on polypeptides that "consist essentially of" the amino acid sequence of SEQ ID NO: 1. Because there is no limitation on the language "consisting essentially of" in the application, this language is read as being equivalent to "comprising." See, MPEP 2111.03. The present application indicates that polypeptides comprising SEQ ID NO: 1 can include fusions of the polypeptide to a tag, such as FLAG. Page 11, paragraph [0033]. Thus, the rejected

claims read on antibodies that bind to the FLAG sequence. Such antibodies are anticipated by the '864 patent. See e.g., column 30, lines 39-40. The reference therefore anticipates the indicated claims.

12. **(New Rejection)** Claims 52-55 and 57-62 rejected under 35 U.S.C. 102(b) as being anticipated by Boyd (US 6,193,982) in light of Ziolkowska et al. (Acta Biochim Pol 53: 617-26). These claims read on antibodies that bind to the scytovirin of claim 1, particularly where the antibodies comprise an internal image of HIV gp120, and methods of using such to inhibit infection of a mammal.

Boyd teaches antibodies that comprise an internal image of HIV gp120, and methods of administrating such to raise an anti-HIV immune response. Claims. While the reference indicates that the antibodies bind to a different anti-viral protein, the teachings of Ziolkowska indicate that both the cyanovirin or the patent and the scytovirin of the present application bind to the carbohydrate moieties attached to the HIV gp120 glycoprotein. Based on these teachings, it would be inherent that the antibodies of the patent would also be capable of binding to the polypeptides of the present application. The patent also indicates that the antibodies may be formulated with an imunostimulant. Column 23, lines 24-27. The patent also teaches anti-Flag antibodies as disclosed above. See e.g., column 27, lines 57-60. The reference therefore anticipates the indicated claims.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. **(New Rejection)** Claims 52-55 and 57-62 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,193,982 in light of Ziolkowska. The claims of the patent anticipate, or render obvious, the presently rejected claims as described above in the rejection under 35 U.S.C. 102(b). The present claims are therefore also rejected for double patenting over the patent claims as being anticipated by the copending claims, or for representing obvious variants of those claims.

Conclusion

15. No claims are allowed. Claims 2, 17, 53, and 54 are objected to as depending from a rejected claim.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Z. Lucas/
Patent Examiner, AU 1648